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Williamson, J. S., Ambler, G. K., Twine, C. P., Williams, I. M., & Williams, G. L. (2018). Elective Repair of Abdominal Aortic Aneurysm and the Risk of Colonic Ischaemia: Systematic Review and Meta-Analysis. *European Journal of Vascular and Endovascular Surgery*, *56*(1), 31-39. https://doi.org/10.1016/j.ejvs.2018.03.005

Peer reviewed version

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Link to published version (if available):
10.1016/j.ejvs.2018.03.005

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Elective repair of abdominal aortic aneurysm and the risk of colonic ischaemia: systematic review and meta-analysis

Short title

Colonic ischaemia in EVAR vs open repair

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Systematic review

Funding source/Conflict of Interest - None declared

Word Count

What does this study/review add to the existing literature and how will it influence future clinical practice

This is the largest and most contemporary analysis which demonstrates colonic ischaemia (CI) occurs more frequently in open repair (2.1-3.6%) than in EVAR (0.5-1%) in the elective setting. The majority of cases present within 7 days. There is insufficient evidence to determine if there is a difference in rates of reoperation for CI between the two techniques but when colectomy is required, the mortality rate is high. Most randomised trials of OR vs EVAR do not specifically report colonic ischaemia and its sequelae and this should be addressed by future trials given the high morbidity and mortality.

ABSTRACT

Introduction

Colon ischaemia (CI) is a significant complication of open (OR) and endovascular (EVAR) repair of abdominal aortic aneurysm (AAA). With a rapid increase in EVAR uptake, contemporary data demonstrating the differing rates and outcomes of CI between EVAR and OR, particularly in the elective setting are lacking. We aimed to characterise the risk and consequences of CI in elective AAA repair comparing EVAR with OR.

Method

A systematic review and meta analysis of the literature was performed using the Cochrane collaboration protocol and reported *as per* the PRISMA guidelines.

PubMed, MedLine and EMBASE were searched for studies reporting CI rates after elective AAA repair. Ruptured AAA were excluded from analysis.

Results

13 studies reporting specific outcomes of CI after elective AAA repair, containing 162750 evaluable patients (78151 EVAR and 84599 OR) were included. All studies found a higher risk of CI with OR compared to EVAR. Three studies performed confounder adjustment with CI rates of 0.5-1% vs 2.1-3.6% (EVAR vs OR) and combined odds ratio of 2.7 (2.0-3.5) for the development of CI with OR vs EVAR. The majority of cases of CI occurred within 30 days and are associated with variable mortality (0 to 73%) and reintervention rates (27-54%). GRADE assessment of evidence strength was very low for all outcomes. There was a high degree of heterogeneity between studies both methodologically and in terms of CI rates, reintervention, mortality and time to development of CI.

Conclusions

EVAR is associated with reduced incidence of CI compared with OR.

Introduction

Despite recent advances in the treatment of abdominal aortic aneurysm (AAA) the postoperative risk of colonic ischaemia (CI) remains. Colonic ischaemia is a serious complication and a significant cause of postoperative mortality. (1-3).

Reported rates of colonic ischaemia after intervention for AAA vary between trials, as does its relationship with mortality. It is currently unclear whether CI is more common after open repair or EVAR, with overlapping rates quoted in different trials (4-7). Colonic ischaemia has previously been considered to be more common after OR than EVAR and looking explicitly at ruptured AAA, a Cochrane review found a decreased risk of CI after EVAR as compared to OR (Odds ratio 0.39, 95% CI 0.07-2.11), however much of the data was produced by a single trial with only 116 patients(8). Furthermore, the acceptance of EVAR has increased significantly in the last few years(9, 10) and so the rate of colonic ischemia may have changed.

Recent randomised controlled trials of EVAR vs OR were powered to detect differences in survival and all cause mortality(11), however, CI is relatively rare and there is therefore little high quality or powered data to reflect contemporary rates of colonic ischaemia. Furthermore, the incidence of CI may increase with time after EVAR, especially with type 2 endoleak intervention and embolization of the inferior mesenteric artery.

The aim of this meta-analysis was to compare and pool data from the literature to identify the contemporary incidence of postoperative colonic ischaemia after elective EVAR and open AAA repair, and to assess whether there is a relationship between the type of AAA intervention and the time when CI develops.

Methods

Data sources, search strategy and selection criteria

A systematic review was undertaken utilising the Cochrane collaboration specified protocol(12), and reported *as per* the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for the conduct of meta-analyses of interventional studies(13). The following sources were searched without date restrictions: PubMed, Medline via OVID, Embase, the Cochrane Library Database and the Current Controlled Trials register. Details of the protocol for this systematic review were registered on PROSPERO and can be accessed at www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017069624

Studies reporting CI rates after elective AAA repair were included. Exclusion criteria included articles where ruptured aneurysms could not be analysed separately and aneurysms involving the suprarenal aorta. Definition of colonic ischaemia was based on clinically detectable features of ischaemic colitis including abdominal pain and bloody diarrhoea with or without endoscopic confirmation. There was no limitation on publication type or language in the initial search. An extensive search was also conducted using the 'related articles' function in PubMed, of which the results were limited to human research, with review articles excluded. The last search date was 10th June 2017. Outcome events were captured

when two or more papers presented extractable data. Non-English language papers were subsequently excluded, as were papers arising, or suspected of arising, from duplicate publications.

Data extraction, and outcome measures

Data extraction and assessment of methodological quality was performed independently by two authors. On cases of disagreement a consensus was reached amongst all authors. Extracted data consisted of: first author, year of study, study type and design (including if retrospective or prospective, single or multiple centres, if consecutive patients were enrolled), number of participants, modality of treatment (EVAR or OR), numbers of patients experiencing colonic ischaemia, confounder corrected odds ratio or relative risk of colonic ischaemia, number, nature and timing of reinterventions for treatment of CI. Where available data regarding the perioperative patency, embolization and/or endoleak intervention to visceral arteries were extracted. Data were extracted at one year follow up where available, or if not given, at maximal follow up.

Outcome measures were defined as:

1. CI rate
2. Mortality related to CI
3. Reintervention rate for CI and any consequences
4. Time to CI

Assessment of study quality and evidence rating

Study quality was assessed using the Downs and Black checklist, which assigns points depending on the quality of design (maximum eleven points), external validity (maximum three points), study bias (maximum seven points), confounding and selection bias (maximum six points) and study power (maximum 5 points)(14). Studies with a score ≥ 17 were considered to be of higher quality.

Rating of the quality of evidence and strength of recommendation was undertaken using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system, *as per* Cochrane collaboration recommendation(15). Quality was assessed depending on: risk of bias, indirectness of evidence, heterogeneity, imprecision of results and publication bias. Cohort studies, by definition, have a 'low' quality of evidence prior to further quality assessment. The presence of one or more serious limitations results in a 'very low' grade of evidence. A serious effect on quality of evidence was considered to occur when >50 per cent of included papers evidenced a risk of bias. Inconsistency was defined as an I^2 of greater than 50 per cent. Indirectness was assumed not to occur in this setting. Imprecision was defined as less than 150 patients in either cohort. A serious effect on quality of evidence was considered to occur when greater than 50 per cent of included papers evidenced a risk of imprecision.

Statistical analysis

Meta-analysis was undertaken in Review Manager version 5.3.5 (RevMan; Nordic Cochrane Centre, Copenhagen, Denmark). Meta-analysis was performed for dichotomous data where counfounder corrected odds ratios or relative risks were available, using odds ratio (OR) as the summary statistic, and reported with 95 per

cent confidence intervals (CI), in line with the recommendations of the Cochrane Handbook (10). Random-effects models were used where significant heterogeneity between studies was detected. Heterogeneity was assessed using an I^2 calculation(16).

Our protocol specified that publication bias was to be assessed using funnel plots for outcomes with more than ten studies(17), though there were no outcomes which satisfied this criterion, so no funnel plots are presented.

Results

Paper search and selection process

The initial search yielded a total of 1190 results, of which 48 papers were retrieved for full evaluation. A total of 13 papers fulfilled the inclusion criteria and were included in the subsequent review(1, 4-6, 18-26). See figure 1. Excluded papers of note include 5 studies in which ruptured and elective AAA data could not be separated(27-31). There were 3 randomised controlled trials(2, 3, 32) and 4 retrospective large case series(33-36) in which GI complications of AAA repair were reported but no specific data referring to ischaemic colitis were recorded. All included studies were case series reporting outcomes of ischaemic colitis after elective AAA repair either with EVAR, OR, or both. A total of 84599 OR and 78151 EVAR were available for evaluation.

Study design and baseline characteristics

Study characteristics are given in Table 1. There were 6 studies(1, 4, 5, 24-26) comparing outcomes for patients treated with EVAR (76520 patients) and OR (80501). Three of these performed confounder adjustment, one by multivariate propensity matching of the cohorts(1) and the other two via multivariate modelling (4, 25). There were 4 studies reporting only EVAR(6, 18, 20, 21) (1631 patients) and 3 studies reporting only OR outcomes(19, 22, 23) (4098 patients). Data for patients crossing over from EVAR to OR were not presented in any study. Diagnosis of colon ischaemia was made on clinical grounds in all studies with endoscopic confirmation in 4 studies(6, 18, 20, 21).

There were three high quality papers as determined by the Downs and Black assessment presented in table 1(2, 6, 19). GRADE quality assessment was 'very low' for all outcomes (Table 3).

Outcomes

Outcome data for each study are presented in Table 2.

Colonic ischaemia rate

Thirteen studies reporting specific outcomes of CI after elective AAA repair, containing 162750 patients (78151 EVAR and 84599 OR) were included. No randomised controlled studies reported specific CI outcomes. Six retrospective case studies directly compared CI in elective AAA between EVAR and OR. Confounder correction was performed in three of these studies, making them suitable for formal meta-analysis (Figure 2). Colonic ischaemia rates in these three studies for EVAR (71186 patients) vs OR (78436 patients) were 0.5% vs 2.2%(4), 1% vs 2.1%(1) and 0.6% vs 3.6%(25).

Odds ratios (95% confidence intervals) for the development of CI with OR versus EVAR were 2.19 (1.87-2.56)(1), 3.1 (2.7-3.7)(4) and 2.9 (1.8-4.7)(25) in the three studies which employed methods to correct for confounding, giving a combined odds ratio of 2.7 (2.0-3.5).

There was significant heterogeneity between these three studies, both methodologically and in terms of rates (I^2=80%). In the three studies which did not employ confounder correction, odds ratios were 1.003 (0.997-1.010)(5), 4.59 (0.55-38.5)(24) and 3.07 (1.17-7.98)(26).

A further 7 retrospective case series were included in which 3(19, 22, 23) reported CI rates in a total of 4098 elective open repairs and 4(6, 18, 20, 21) reported CI rates in a total of 1631 elective EVAR. Studies considering open repairs consistently published rates of CI which were higher than those studies considering EVAR.

CI mortality

There were 3 studies comparing EVAR to OR and of these, one reported no CI related mortality(5) and two reported significant mortality rates in the CI group: 25/107 (23%) in one study(25) and 370/1941 (19%) in the other(4). In this latter paper, mortality associated with colectomy was significantly higher following EVAR than OR (73% vs 51%, $p<0.05$), however, conservative management was associated with increased survival following EVAR compared to OR (84% vs 78%, $p<0.05$). There were 4 studies reporting CI mortality in EVAR only patients(6, 18, 20, 21) and of 27 cases of CI in these 4 papers, 11 patients (41%) died. There were

2 studies reporting CI mortality in OR only patients(19, 23) and none of 3 patients with CI died. See table 2 for individual study mortality rates.

Reintervention rate for CI

Re-intervention data were available in 11 papers. See table 2. Six papers reported reintervention rates for patients undergoing both EVAR and OR and none demonstrated a significant difference in colectomy rates following EVAR compared to OR. Reported colectomy rates were variable between 27% and 100%. In one(1), specific reintervention rates for colon ischaemia were not available. However, rates of bowel resection as a complication of surgery were available and patients undergoing EVAR were less likely to undergo a small bowel resection than those undergoing OR in the first 4 years post aneurysm repair (3% vs 3.4%,$p<0.05$). In 4 papers reporting reintervention rates in 1631 patients undergoing EVAR only(6, 18, 20, 21), 11/27 with CI (41%) underwent emergency colectomy. A single paper(19) containing 120 patients reporting on OR only reported a single patient with CI, treated with surgery.

Time to colonic ischaemia

Seven studies reported the timing of initial signs and symptoms of colonic ischaemia. Hynes et al(26) looked at the timing of re-operations within the first 30 days, finding that 5/10 patients requiring intervention for CI following OR did so within the first 24 hours and the remainder required intervention within the first week. Rates were similar following EVAR, with 4/14 in the first 24 hours, 13/14 in the first week and only 1 patient requiring reintervention between 7 and 30 days. Four papers contained data on timing of development of CI after EVAR

without comparison to OR (6, 18, 20, 21). Eighty one percent (22/27) of these cases occurred within 30 days and nineteen percent (5/27) occurred after 30 days. Limited data was available for CI in OR without comparison to EVAR, with only 2 studies reporting on 423 patients undergoing OR. These reported 2 cases of CI, one of which was at 11 days and one was after 30 days(5, 19).

Perioperative visceral arterial status

There was a single study reporting the effect of endoleak on CI and found colonic ischaemia was associated with type 3 but not type 2 endoleak at the end of the procedure(25). It was not possible to determine if reintervention was performed in these cases. Four studies recorded the preprocedure IMA patency and whether IMA embolization had been performed(6, 18, 21, 25). It was not possible to extract data to draw specific comparisons of the effect of IMA embolization on CI, however in one paper, all patients who went on to develop CI following EVAR had patent IMA preoperatively(21) whereas the others reported between 62% and 91% of those who developed CI following EVAR had pre-existing IMA occlusions. Six studies reported on the effect of internal iliac artery (IIA) embolization on CI. Of these, 2 reported a higher risk of CI with unilateral IIA embolization(18, 25), whereas 4 studies reported no difference in risk of CI with either uni or bilateral IIA embolization(6, 20, 21, 24).

Discussion

This analysis has identified several case series, which have compared CI rates between elective EVAR and OR. These studies are of variable quality, GRADE assessment was very low for all outcomes and only three performed any type of confounder adjustment. Meta-analysis of results from these studies suggests that CI rates may be significantly higher after OR than EVAR. The outcome data for over 150000 patients in 11 studies also demonstrate a clear advantage of EVAR in terms of reduced frequency of CI. Although it was not possible to control for factors such as comorbidity or IMA status, it is clear that in general EVAR carries a lower risk of CI.

These results are comparable to a recent review by Lee et al(37) who found a reduced likelihood of CI after EVAR compared to OR (Relatve Risk 0.22, 0.12-0.39, $p<0.001$), although this analysis included both ruptured and elective AAA and contained older studies with a smaller number of patients and did not employ confounder correction. For ruptured AAA, a recent Cochrane review found a decreased risk of CI after EVAR as compared to OR (Odds ratio 0.39, 95% CI 0.07-2.11), however this relied upon a single randomised trial with only 116 patients (8, 38).

Perioperative mortality was significantly lower in EVAR vs OR in a recent meta-analysis of four randomised trials comparing EVAR with OR(11), however, this early survival advantage is lost at 3 years, mainly due to aneurysm specific complications, although patients with low ABPI experienced worse long term survival with EVAR compared to OR. There was insufficient data to determine

whether colonic ischaemia was a factor in this. From our analysis, when CI occurs, it is usually identified within 30 days and is associated with a significant mortality rate, particularly where colectomy is required and it may be that earlier recognition and treatment of this condition could improve outcomes.

It was noted that of several large randomised controlled trials, there were no available data for CI rates; instead the authors reported less specific complications such as need for re-laparotomy or GI intervention (2, 3, 32, 39, 40). Of note, there was an increased risk of small bowel resection following OR than EVAR in one large series and although the cause was not identified, there was an associated increased risk of adhesional and hernia related bowel obstruction after OR and this is likely to be related. There were insufficient data to determine whether reintervention rates for treatment of CI differed between OR and EVAR and were broadly similar in the larger series. We therefore recommend that future RCT's specifically report CI outcomes when comparing both procedures given the high mortality resulting from this condition. This is particularly important as there is emerging evidence that more patients with prohibitive risk factors for surgery are being offered EVAR(41). The benefit of a selective approach to EVAR use in more frail patients is not clear (42) and the relative contributions of comorbidity and specific complications such as CI to survival and long term outcomes from both EVAR and OR will be more difficult to interpret.

The physiological basis of CI after AAA repair is likely multifactorial and this may explain the differences in CI rates between procedures. In open surgery a significant factor is aortic cross clamping giving rise to ischaemia and reperfusion injury of the colon. One study found a 3 fold increase in colonic

mucosal apoptosis in biopsies obtained immediately after surgery as compared to EVAR as well as significant rises in peripheral proinflammatory cytokines including TNF alpha compared with no evidence of apoptosis and much lower cytokine release following EVAR(43) . In the case of EVAR, a possible cause of CI is sacrifice of the inferior mesenteric and rarely, the internal iliac arteries. The effect of IMA sacrifice on CI is not clear and is commonly performed in both EVAR and OR. One study attempted to address this by randomising 160 patients to IMA ligation or reimplantation during OR and found no difference in CI rates(44). During EVAR, occasionally one and rarely both internal iliac arteries may be sacrificed. A case control study demonstrated a tendency towards higher risk of CI after bilateral internal iliac artery ligation as opposed to unilateral ligation in open surgery(28). However, a review of 278 EVARs found that of the 8 patients who developed CI, only one had undergone internal iliac artery embolization and the remaining 121 who underwent uni or bilateral internal iliac embolization had no evidence of CI(6). Furthermore, of the 8 with CI, 4 displayed evidence of distal microvascular emboli within colonic arterioles presumed a result of dislodged atheroma from the aorta or access vessel. Preoperative imaging demonstrated IMA occlusions in 3 of 4 patients and the embolic pathway was therefore presumed to be via patent internal iliac arteries. In the present analysis, data regarding the effect of perioperative visceral arterial embolization were limited and contradictory and no firm conclusions can be drawn from the available literature. Various techniques have been employed to improve detection and reduce the risk of CI including intraoperative IV fluorescein(45), early postoperative sigmoidoscopy(7) and intraoperative laser doppler flowmetry(46) although none have yet entered routine clinical practice.

Furthermore, as there is no ability to observe the colon during the EVAR procedure, detection of CI is difficult initially which may lead to delayed diagnosis with more serious consequences, whereas during open surgery, colon ischaemia may be detected intraoperatively and measures such as colectomy or IMA reimplantation undertaken which will affect reported CI rates. .

Factors contributing to CI are emergency open repair for rupture and associated parameters such as blood loss, pre-existing renal and respiratory morbidity and length of surgery (27, 30, 47).

The strengths of the current analysis are that a large number of patient outcomes were available for analysis and all demonstrated a higher rate of CI with OR. However, most studies were poorly designed with limited or no evidence of cohort matching. Most did not clearly describe how colonic ischaemia was diagnosed and definitions were largely based on clinical grounds with only limited description of endoscopic confirmation.

It is notable that many studies did not report the timing of onset of CI. Most studies did not employ routine post operative sigmoidoscopy and it is possible that minor and self limiting CI may not have been detected in some series and only those with severe CI included in the analysis thereby increasing the reported mortality and reintervention rates. Furthermore, several papers reported onset of CI more than 30 days after initial treatment and it is possible that this represents a different pathological process and it was not possible to accurately confirm this from the data available. A sensitivity analysis was not

possible due to the limited number of directly comparable studies. Furthermore, it was not possible to extract and meta analyse data for confounding factors such as renal impairment, comorbidity, management of endoleaks, IMA ligation and/or reimplantation, transfusion requirements, length of stay and operative time or technique including use of intraoperative Doppler monitoring of colonic perfusion or mesenteric artery reimplantation.

Conclusion

In an elective setting, EVAR is associated with reduced frequency of CI compared with OR. CI is associated with significant mortality. When emergency colectomy is required, the mortality rises to over 50% in most studies. It is not clear if there is a difference in CI related mortality or colectomy rates between EVAR and OR, however, when it does occur, most cases present within 7 days for both procedures.

Figure Legends

PRISMA 2009 Flow Diagram

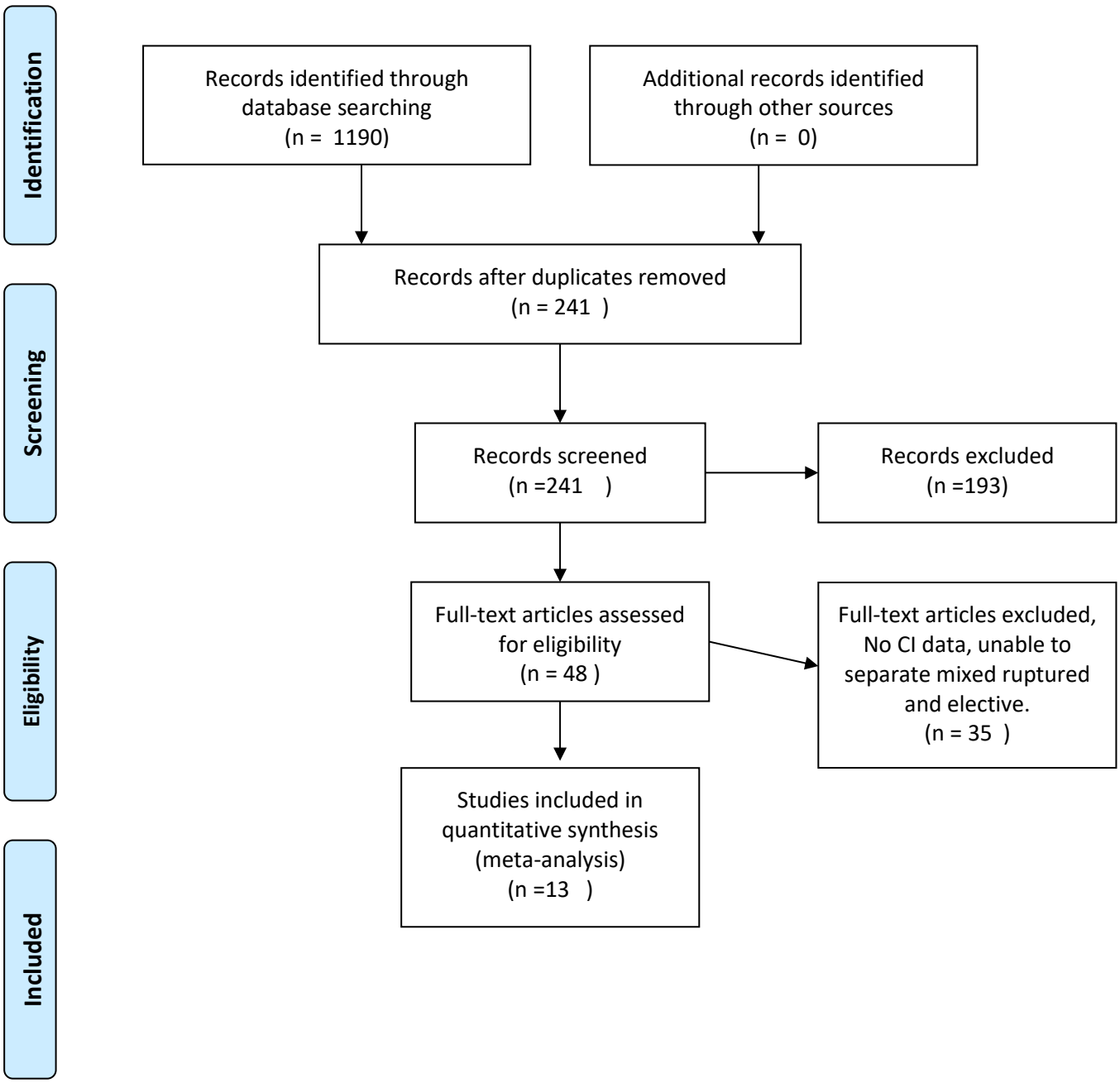

Figure 1. Inclusion process for identified studies

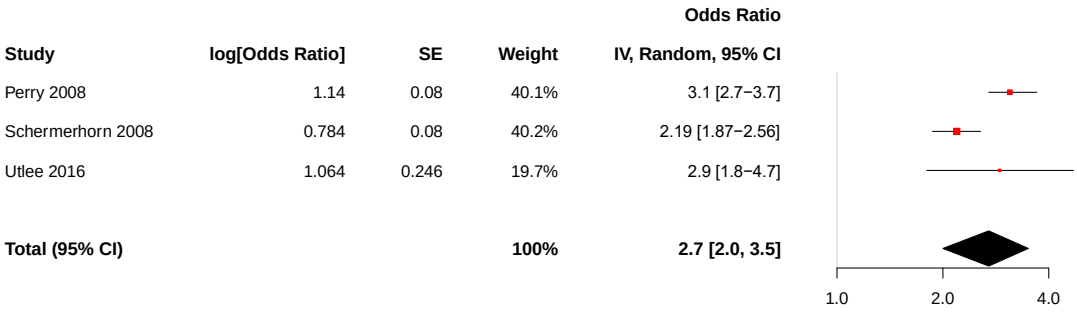

Figure 2. Forest plot comparing rates of CI between OR and EVAR in studies employing techniques for multivariate confounder correction. Higher odds ratios imply higher rates among patients undergoing OR. Heterogeneity: Tau^2 = 0.05; Chi^2 = 10.06, df = 2 (P = 0.007); I^2 = 80%. Test for overall effect: Z = 6.81 (P < 0.00001).

Table 1. Table 1. Study Characteristics, demographic data and Downs and Black scores for each paper. Outcome 1. Colon ischaemia (CI) rate, 2. CI mortality rate, 3. Reintervention rate, 4. Time to CI

Table 2. Outcome data for each study

Table 3. GRADE analysis and assessment of quality of evidence. Risk of bias was assessed for each included paper, and was assumed to be present when a non-consecutive, or non-propensity matched cohort was analysed, or follow up did not reach 12 months.

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